INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We make Indiana a cleaner, healthier place to live.

Joseph E. Kernan
Governor

Lori F. Kaplan
Commissioner

100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
(317) 232-8603
(800) 451-6027
www.in.gov/idem

March 5, 2004

TO: Interested Parties / Applicant

RE: Baxter Pharmaceutical Solutions, LLC / MSOP105-16441-00040

FROM: Paul Dubenetzky
Chief, Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

(1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
(2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
(3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

(1) the name and address of the person making the request;
(2) the interest of the person making the request;
(3) identification of any persons represented by the person making the request;
(4) the reasons, with particularity, for the request;
(5) the issues, with particularity, proposed for considerations at any hearing; and
(6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER.dot 9/16/03

NEW SOURCE CONSTRUCTION PERMIT
and
MINOR SOURCE OPERATING PERMIT
OFFICE OF AIR QUALITY

Baxter Pharmaceutical Solutions LLC
927 South Curry Pike
Bloomington, Indiana 47403

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this permit.

This permit is issued to the above mentioned company under the provisions of 326 IAC 2-1.1, 326 IAC 2-5.1, 326 IAC 2-6.1 and 40 CFR 52.780, with conditions listed on the attached pages.

Operation Permit No.: MSOP 105-16441-00040	
Issued by: Original Signed by Paul Dubenetzky Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: March 5, 2004 Expiration Date: March 5, 2009

TABLE OF CONTENTS

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.1.1 Preventive Maintenance Plan [326 IAC 1-6-3]

D.2 FACILITY OPERATION CONDITIONS - Source Combustion Units

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.2.1 Particulate Matter Emissions [326 IAC 6-2-4]

D.2.2 Preventive Maintenance Plan [326 IAC 1-6-3]

Record Keeping and Reporting Requirements [326 IAC 2-5.1-3(e)(2)] [326 IAC 2-6.1-5(a)(2)]

D.2.3 Notification Requirements, Boiler HSS-03BR [40 CFR 60.48c(a), 326 IAC 12]

D.2.4 Record Keeping Requirements, Boiler HSS-03BR [40 CFR 60.48c(g) and (i), 326 IAC12]

Annual Notification
Malfunction Report

SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-5.1-3(c)] [326 IAC 2-6.1-4(a)]

The Permittee owns and operates a stationary third party pharmaceutical manufacturing operation.

Authorized Individual:	Lee Karras
Source Address:	927 South Curry Pike, Bloomington, Indiana 47403
Mailing Address:	P.O. Box 3068, Bloomington, Indiana 47402
General Source Phone:	812-333-0887
SIC Code:	2834
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Minor Source, under PSD or Emission Offset Rules; Minor Source, Section 112 of the Clean Air Act

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

(a) One (1) pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;

(2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging;

(3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;

(4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;

(5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging; and

(6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

(b) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as LES #1 and LES#2, located in Building A.

(c) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as HSS-01BR and HSS-02BR, located in Building A.

(d) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as Bryan #1 and Bryan #2, located in Building C.

(e) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as HSS-03BR, located in Building C.

(f) One (1) 0.88 MMBtu/hr natural gas tangential fired boiler, identified as BLDG E Boiler, located in Building E.

(g) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BLDG F Boiler, located in Building F.

(h) Two (2) 3.81 MMBtu/hr natural gas fired boilers, identified as D-1 and D-2, located in Building D.

(i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.

(j) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.

(k) One (1) 5.97 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.

A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is not required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

(a) It is not a major source, as defined in 326 IAC 2-7-1(22);

(b) It is not an affected source under Title IV (Acid Deposition Control) of the Clean Air Act, as defined in 326 IAC 2-7-1(3); and

(c) It is not a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONDITIONS

THIS SECTION OF THE PERMIT IS BEING ISSUED UNDER THE PROVISIONS OF 326 IAC 2-1.1 AND 40 CFR 52.780, WITH CONDITIONS LISTED BELOW.

B.1 Permit No Defense [IC 13]

This permit to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

B.2 Definitions

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations IC 13-11, 326 IAC 1-2, and 326 IAC 2-1.1-1 shall prevail.

B.3 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this permit becomes effective upon its issuance.

B.4 Revocation of Permits [326 IAC 2-1.1-9(5)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this permit if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

B.5 Permit Term and Renewal [326 IAC 2-6.1-7(a)][326 IAC 2-1.1-9.5]

This permit is issued for a fixed term of five (5) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions of this permit do not affect the expiration date.

The Permittee shall apply for an operation permit renewal at least ninety (90) days prior to the expiration date. If a timely and sufficient permit application for a renewal has been made, this permit shall not expire and all terms and conditions shall continue in effect until the renewal permit has been issued or denied.

B.6 Modification to Permit [326 IAC 2]

Notwithstanding the Section B condition entitled “Minor Source Operating Permit”, all requirements and conditions of this construction permit shall remain in effect unless modified in a manner consistent with procedures established for modifications of construction permits pursuant to 326 IAC 2 (Permit Review Rules).

B.7 Minor Source Operating Permit [326 IAC 2-6.1]

This document shall also become a minor source operating permit pursuant to 326 IAC 2-6.1 when, prior to start of operation, the following requirements are met:

(a) The attached Affidavit of Construction shall be submitted to the Office of Air Quality (OAQ), Permit Administration & Development Section.

(1) If the Affidavit of Construction verifies that the facilities covered in this Construction Permit were constructed as proposed in the application, then the facilities may begin operating on the date the Affidavit of Construction is postmarked or hand delivered to IDEM.

(2) If actual construction of the emission units differs from the construction proposed in the application, the source may not begin operation until the permit has been revised pursuant to 326 IAC 2-6.1-6 and an Operation Permit Validation Letter is issued.

(b) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.

(c) Upon receipt of the Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section, the Permittee shall attach it to this document.

(d) The operation permit will be subject to annual operating permit fees pursuant to 326 IAC 2-1.1-7(Fees).

B.8 Annual Notification [326 IAC 2-6.1-5(a)(5)]

(a) Annual notification shall be submitted to the Office of Air Quality stating whether or not the source is in operation and in compliance with the terms and conditions contained in this permit.

(b) Noncompliance with any condition must be specifically identified. If there are any permit conditions or requirements for which the source is not in compliance at any time during the year, the Permittee must provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be, achieved. The notification must be signed by an authorized individual.

(c) The annual notice shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted in the format attached no later than March 1 of each year to:

Compliance Branch, Office of Air Quality
Indiana Department of Environmental Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, IN 46206-6015

(d) The notification shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

B.9 Preventive Maintenance Plan [326 IAC 1-6-3]

(a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) within ninety (90) days after issuance of this permit, including the following information on each emissions unit:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The PMP extension notification does not require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) The Permittee shall implement the PMPs, including any required record keeping, as necessary to ensure that failure to implement a PMP does not cause or contribute to an exceedance of any limitation on emissions or potential to emit.

(c) A copy of the PMP's shall be submitted to IDEM, OAQ, upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ, may require the Permittee to revise its PMP whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions or potential to emit. The PMP does not require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation, Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.10 Permit Revision [326 IAC 2-5.1-3(e)(3)] [326 IAC 2-6.1-6]

(a) Permit revisions are governed by the requirements of 326 IAC 2-6.1-6.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application shall be certified by an "authorized individual" as defined by 326 IAC 2-1.1-1.

(c) The Permittee shall notify the OAQ within thirty (30) calendar days of implementing a notice-only change. [326 IAC 2-6.1-6(d)]

(d) No permit amendment or modification is required for the addition, operation or removal of a nonroad engine, as defined in 40 CFR 89.2.

B.11 Inspection and Entry [326 IAC 2-5.1-3(e)(4)(B)] [326 IAC 2-6.1-5(a)(4)][IC 13-14-2-2] [IC 13-30-3-1]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a permitted source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under this title or the conditions of this permit or any operating permit revisions;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any processes, emissions units (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit or any operating permit revisions;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.12 Transfer of Ownership or Operation [326 IAC 2-6.1-6(d)(3)]

Pursuant to [326 IAC 2-6.1-6(d)(3)] :

(a) In the event that ownership of this source is changed, the Permittee shall notify IDEM, OAQ, Permits Branch, within thirty (30) days of the change.

(b) The written notification shall be sufficient to transfer the permit to the new owner by an notice-only change pursuant to 326 IAC 2-6.1-6(d)(3).

(c) IDEM, OAQ, shall issue a revised permit.

The notification which shall be submitted by the Permittee does require the certification by the "authorized individual" as defined by 326 IAC 2-1.1-1.

B.13 Annual Fee Payment [326 IAC 2-1.1-7]

(a) The Permittee shall pay annual fees to IDEM, OAQ within thirty (30) calendar days of receipt of a billing.

(b) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, I/M & Billing Section), to determine the appropriate permit fee.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) pounds per hour [326 IAC 6-3-2

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Permit Revocation [326 IAC 2-1.1-9]

Pursuant to 326 IAC 2-1.1-9 (Revocation of Permits), this permit to construct and operate may be revoked for any of the following causes:

(a) Violation of any conditions of this permit.

(b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this permit.

(c) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of this permit shall not require revocation of this permit.

(d) Noncompliance with orders issued pursuant to 326 IAC 1-5 (Episode Alert Levels) to reduce emissions during an air pollution episode.

(e) For any cause which establishes in the judgment of IDEM, the fact that continuance of this permit is not consistent with purposes of this article.

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.4 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326

IAC 6-4 (Fugitive Dust Emissions).

C.5 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

The Permittee shall comply with the applicable requirements of 326 IAC 14-10, 326 IAC 18, and 40 CFR 61.140.

Testing Requirements

C.6 Performance Testing [326 IAC 3-6]

(a) Compliance testing on new emissions units shall be conducted within 60 days after achieving maximum production rate, but no later than180 days after initial start-up, if specified in Section D of this approval. All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAQ.

A test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date.

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14 days) prior to the actual date.

(c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAQ, if the source submits to IDEM, OAQ, a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.7 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U.S. EPA.

Compliance Monitoring Requirements

C.8 Compliance Monitoring [326 IAC 2-1.1-11]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. All monitoring and record keeping requirements not already legally required shall be implemented when operation begins.

C.9 Monitoring Methods [326 IAC 3][40 CFR 60][40 CFR 63]

Any monitoring or testing required by Section D of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60, Appendix B, 40 CFR 63, or other approved methods as specified in this permit.

Record Keeping and Reporting Requirements

C.10 Malfunctions Report [326 IAC 16-2]

Pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

(a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) or appointed representative upon request.

(b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAQ, using the Malfunction Report Forms (2 pages). Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.

(c) Failure to report a malfunction of any emission control equipment shall constitute a violation of 326 IAC 1-6, and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).

(d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. [326 IAC 1-2-39]

C.11 General Record Keeping Requirements [326 IAC 2-6.1-5]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented when operation begins.

C.12 General Reporting Requirements [326 IAC 2-1.1-11] [326 IAC 2-6.1-2] [IC 13-14-1-13]

(a) Reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality

100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(b) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

(c) Unless otherwise specified in this permit, any quarterly or semi-annual report required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. The report(s) does(do) not require the certification by an “authorized individual” as defined by 326 IAC 2-1.1-1(1).

(d) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

The pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
(B) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging;
(3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
(4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
(5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging; and
(6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

D.1.1 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this equipment and any control devices.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

(1) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as LES #1 and LES#2, located in Building A.
(2) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as HSS-01BR and HSS-02BR, located in Building A.
(3) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as Bryan #1 and Bryan #2, located in Building C.
(4) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as HSS-03BR, located in Building C.
(5) One (1) 0.88 MMBtu/hr natural gas tangential fired boiler, identified as BLDG E Boiler, located in Building E.
(6) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BLDG F Boiler, located in Building F.
(7) Two (2) 3.81 MMBtu/hr natural gas fired boilers, identified as D-1 and D-2, located in Building D.
(8) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
(9) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
(10) One (1) 5.97 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

D.2.1 Particulate Matter Emissions [326 IAC 6-2-4]

The owner or operator shall, for boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, and BLDGF, limit the PM emissions from each unit to 0.40 lb/MMBtu or less.

D.2.2 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility and its control device.

Record Keeping and Reporting Requirements [326 IAC 2-5.1-3(e)(2)] [326 IAC 2-6.1-5(a)(2)]

D.2.3 Notification Requirements, Boiler HSS-03BR [40 CFR 60.48c(a), 326 IAC 12]

The owner or operator shall submit to the Office of Air Quality, a notification regarding Boiler HSS-03BR. Said notification shall:

(a) include:

(1) the date of construction or reconstruction, the date of anticipated startup, and the date of actual startup, as provided in 40 CFR 60.7; and

(2) the design heat input capacity of the boiler and identification of the fuels combusted in the boiler; and

(b) be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

D.2.4 Record Keeping Requirements, Boiler HSS-03BR [40 CFR 60.48c(g) and (i), 326 IAC 12]

The owner or operator shall, for Boiler HSS-03BR, record and maintain records of the amount of each fuel combusted during each day.

Said records shall be maintained for a minimum period of two years following the date the information is recorded.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH

MINOR SOURCE OPERATING PERMIT
ANNUAL NOTIFICATION

This form should be used to comply with the notification requirements under 326 IAC 2-6.1-5(a)(5).

Company Name:	**Baxter Pharmaceutical Solutions LLC**
Address:	**927 South Curry Pike**
City:	**Bloomington, Indiana 47403**
Phone #:	**812-333-0887**
MSOP #:	**105-16441-00040**

I hereby certify that Baxter Pharmaceutical Solutions LLC is
? still in operation.
? no longer in operation.

I hereby certify that Baxter Pharmaceutical Solutions LLC is
? in compliance with the requirements of MSOP 105-16441-00040.
? not in compliance with the requirements of MSOP 105-16441-00040.

Authorized Individual (typed):
Title:
Signature:
Date:

If there are any conditions or requirements for which the source is not in compliance, provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be achieved.

Noncompliance:

MALFUNCTION REPORT

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
FAX NUMBER - 317 233-5967

This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE IT HAS POTENTIAL TO EMIT 25 TONS/YEAR PARTICULATE MATTER ?_____, 25 TONS/YEAR SULFUR DIOXIDE ?_____, 25 TONS/YEAR NITROGEN OXIDES?_____, 25 TONS/YEAR VOC ?_____, 25 TONS/YEAR HYDROGEN SULFIDE ?_____, 25 TONS/YEAR TOTAL REDUCED SULFUR ?_____, 25 TONS/YEAR REDUCED SULFUR COMPOUNDS ?_____, 25 TONS/YEAR FLUORIDES ?_____, 100TONS/YEAR CARBON MONOXIDE ?_____, 10 TONS/YEAR ANY SINGLE HAZARDOUS AIR POLLUTANT ?_____, 25 TONS/YEAR ANY COMBINATION HAZARDOUS AIR POLLUTANT ?_____, 1 TON/YEAR LEAD OR LEAD COMPOUNDS MEASURED AS ELEMENTAL LEAD ?_____, OR IS A SOURCE LISTED UNDER 326 IAC 2-5.1-3(2) ?_____. EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION _____.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC _____ OR, PERMIT CONDITION # _____ AND/OR PERMIT LIMIT OF _____

THIS INCIDENT MEETS THE DEFINITION OF 'MALFUNCTION' AS LISTED ON REVERSE SIDE ? Y N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ? Y N

COMPANY:_____PHONE NO. ( )_____
LOCATION: (CITY AND COUNTY)_____
PERMIT NO. _____ AFS PLANT ID: _____ AFS POINT ID: _____ INSP:_____
CONTROL/PROCESS DEVICE WHICH MALFUNCTIONED AND REASON:_____
_____
_

DATE/TIME MALFUNCTION STARTED: _____/_____/ 19____ _____ AM / PM

ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION: _____

DATE/TIME CONTROL EQUIPMENT BACK-IN SERVICE_____/_____/ 19____ _____ AM/PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO2, VOC, OTHER:_____

ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION: _____

_____
_

MEASURES TAKEN TO MINIMIZE EMISSIONS:_____

_____
_

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS:

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL* SERVICES:_____
CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO PERSONS:_____
CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO EQUIPMENT:_____
INTERIM CONTROL MEASURES: (IF APPLICABLE)_____
_____

MALFUNCTION REPORTED BY:_____TITLE:_____
(SIGNATURE IF FAXED)

MALFUNCTION RECORDED BY:_____DATE:_____TIME:_____

*SEE PAGE 2
PAGE 1 OF 2

Please note - This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

326 IAC 1-6-1 Applicability of rule

Sec. 1. This rule applies to the owner or operator of any facility required to obtain a permit under 326 IAC 2-5.1 or 326 IAC 2-6.1.

326 IAC 1-2-39 "Malfunction" definition

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

***Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:

_____
___
_____

Mail to: Permit Administration & Development Section
Office Of Air Quality
100 North Senate Avenue
P. O. Box 6015
Indianapolis, Indiana 46206-6015

Baxter Pharmaceutical Solutions LLC
P.O. Box 3068
Bloomington, Indiana 47402

Affidavit of Construction

I, _____, being duly sworn upon my oath, depose and say:
(Name of the Authorized Representative)

1. I live in _____ County, Indiana and being of sound mind and over twenty-one (21) years of age, I am competent to give this affidavit.

2. I hold the position of _____ for _____.
(Title) (Company Name)

3. By virtue of my position with _____,I have personal
(Company Name)
knowledge of the representations contained in this affidavit and am authorized to make these representations on behalf of _____ .
(Company Name)

4. I hereby certify that Baxter Pharmaceutical Solutions LCC, 927 South Curry Pike in Bloomington, Indiana 47403, has constructed the third party pharmaceutical manufacturing operation in conformity with the requirements and intent of the permit application received by the Office of Air Quality on August 9, 2002 and as permitted pursuant to **MSOP No. 105-16441-00040** issued on _____

Further Affiant said not.

I affirm under penalties of perjury that the representations contained in this affidavit are true, to the best of my information and belief.

_____
Signature

_____
Date

STATE OF INDIANA)
)SS

COUNTY OF _____)

Subscribed and sworn to me, a notary public in and for _____ County and State of Indiana on this _____ day of _____, 20 _____ .

My Commission expires: _____

_____
Signature

_____
Name (typed or printed)

Indiana Department of Environmental Management
Office of Air Quality

Addendum to the
Technical Support Document for a Minor Source Operating Permit

Source Name: Baxter Pharmaceutical Solutions LLC
Source Location: 927 South Curry Pike, Bloomington, Indiana 47403
County: Monroe
SIC Code: 2834
Operation Permit No.: 105-16441-00040
Permit Reviewer: SDF

On September 19, 2003, the Office of Air Quality (OAQ) had a notice published in the Herald Times, Bloomington, Indiana, stating that Baxter Pharmaceutical Solutions LLC had applied for a Part 70 Operating Permit to operate a stationary third party pharmaceutical manufacturing operation. The notice also stated that the OAQ proposed to issue a permit for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

On October 20, 2003, Baxter Pharmaceutical submitted comments regarding the permit. The following lists the comments, the responses to the comments, and all changes that have been made as a result of the comments. All added information is indicated in bold type. All deleted information is struck-out.

Comment 1:

Upon reviewing the draft permit, Baxter Pharmaceutical realized that some information regarding a proposed plant expansion was inadvertently left out. Thus, Baxter Pharmaceutical wishes to include two additional boilers (D-1 and D-2) and one additional emergency generator (GN02)

Also, in the original application submitted, Baxter Pharmaceutical indicated that the capacities of emergency generators GN03 and GN01 were 74.32 and 6.93 MMBtu/hr, respectively. These capacities are incorrect. The correct capacities are 5.59 and 0.56 MMBtu/hr, respectively. Baxter Pharmaceutical is requesting that these correct capacities be reflected in the source emission estimates.

Response 1:

Boilers D-1 and D-2 and emergency generator GN02 shall be added and the capacities of GN01 and GN03 shall be changed as requested.

Boilers D-1 and D-2 and emergency generator GN02 will generate combustion emissions. The following table lists the criteria and hazardous air pollutant emissions from boilers D-1 and D-2, and emergency generator GN02.

Unit	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	VOC (tons/yr)	NOx (tons/yr)	CO (tons/yr)
D-1	neg.	0.10	neg.	0.10	1.70	1.40
D-2	neg.	0.10	neg.	0.10	1.70	1.40

GN02	0.15	0.09	0.75	0.15	4.78	1.27

Pollutant	D1	D2	GN02	Total
Acetylaldehyde	ND	ND	neg.	neg.
Acrolein	ND	ND	neg.	neg.
Benzene	neg.	neg.	neg.	neg.
Dichlorobenz	neg.	neg.	-	neg.
Formaldehyde	neg.	neg.	neg.	neg.
Hexane	0.03	0.03	-	**0.06**
Napthalene	ND	ND	neg.	neg.
Propylene	ND	ND	neg.	neg.
Toluene	neg.	neg.	neg.	neg.
Lead	neg.	neg.	-	neg.
Cadmium	neg.	neg.	-	neg.
Chromium	neg.	neg.	-	neg.
Manganese	neg.	neg.	-	neg.
Nickel	neg.	neg.	-	neg.
Xylene	ND	ND	neg.	neg.
			Total	**0.06**

The unrestricted potential criteria and hazardous air pollutant emissions from the additional units, each, are less than their respective 326 IAC 2-1.1-3 exempt levels.

There are no new state or federal rules that apply to the proposed additional units. However, adding boilers D-1 and D-2 will change the 326 IAC 6-2-4 PM emission limit for the boilers.

Pursuant to 326 IAC 6-2-4(d), particulate emissions from the combustion of fuel for indirect heating from all facilities receiving permits to construct on or after September 21, 1983 shall be limited by 326 IAC 6-2-4.

The requirements of 326 IAC 6-2-4 apply to Boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, and now D-1 and D-2 because the boilers are sources of indirect heating that will be constructed after the applicable date of September 21, 1983.

Pursuant to 326 IAC 6-2-4, particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

Pt = [1.09] / [Q]^0.26

where: Pt = limit, pounds of particulate matter emitted per million Btu (lb/MMBtu)
Q = total source maximum operating capacity rating in MMBtu/hr heat input (46.46)

The PM emissions from boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, D-1, and D-2, each, shall be limited to 0.40 lb/MMBtu.

The PM emissions from boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, D-1, and D-2, each, are determined to be 0.002 lb/MMBtu which is less than the limit of 0.40 lb/MMBtu.

1.9 lb PM/MMcf * 1 MMcf/1000 MMBtu = 0.002 lb PM/MMBtu

Therefore, compliance with the limit of 326 IAC 6-2-4 is still determined to be achieved.

The following table lists the criteria and hazardous air pollutant emissions from generators GN01 and GN03 determined based on the revised capacities.

Unit	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	VOC (tons/yr)	NOx (tons/yr)	CO (tons/yr)
GN01	-	0.04	0.04	0.05	0.62	0.13
GN03	0.14	0.08	0.70	0.14	4.47	1.19

Pollutant	GN01	GN03	Total
Acetylaldehyde	neg.	neg.	neg.
Acrolein	neg.	neg.	neg.
Benzene	neg.	neg.	neg.
Formaldehyde	neg.	neg.	neg.
Napthalene	neg.	neg.	neg.
Propylene	neg.	neg.	neg.
Toluene	neg.	neg.	neg.
Xylene	neg.	neg.	neg.
1,3 Butadiene	neg.	-	neg.
			neg.

Revising the capacities of emergency generators GN01 and GN03 will not trigger any new applicable requirements or require any changes to any existing requirements.

The source emissions after application of the additional equipment and revised capacities are as follows.

Pollutant	Potential To Emit (tons/year)
PM	0.89
PM10	1.91
SO2	3.08
VOC	24.29

CO	22.28
NO_x	40.15

Pollutant	Potential To Emit (tons/year)
Worst Case Single HAP	0.37
Combined HAPs	0.38

All criteria pollutant UPTE are still less than 100 tons/yr, no single HAP emissions exceed 10 tons/yr, and the combined HAP emissions do not exceed 25 tons/yr. However, the NOx unrestricted potential to emit (UPTE) still exceeds the Minor Source Operating Permit (MSOP) applicable level of 25 tons per year. Therefore, the proposed source shall still be permitted under a Minor Source Operating Permit (MSOP) pursuant to 2-6.1-2.

The Office of Air Quality has determined that adding units to new sources or modifications which have gone through the public notification process can be done without re-public notification provided the combined emissions from the additional units are at exempt levels and there are no new applicable requirements that trigger re-public notification.

Therefore, since the combined emissions from the proposed additional equipment are at exempt levels and there are no applicable requirements associated with the proposed changes which trigger the requirement for re-public notification, the additional units shall be added to the proposed Minor Source Operating Permit (MSOP) without re-public notification.

To incorporate the additional equipment into the permit, the following changes shall be made.

(1) The unit description of Condition A.2 shall be changed as follows to include Boilers D-1 and D-2, and emergency generator GN02 and to include the revised capacities for generators GN01 and GN03.

.....

(e) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as HSS-03BR, located in Building C.

(f) One (1) 0.88 MMBtu/hr natural gas tangential fired boiler, identified as BLDG E Boiler, located in Building E.

(g) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BLDG F Boiler, located in Building F.

(h) Two (2) 3.81 MMBtu/hr natural gas fired boilers, identified as D-1 and D-2, located in Building D.

(~~h~~**i**) One (1) ~~74.32~~ **5.59** MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN03, providing service to Buildings A and C.

(~~i~~**j**) One (1) ~~6.93~~ **0.56** MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN01, providing service to Building B.

(k) One (1) 5.97 MMBtu/hr natural gas emergency generator, identified as GN02, providing service to Building D.

(2) The unit description of Section D.2 shall be changed as follows to include Boilers D-1 and D-2, and emergency generator GN02 and to include the revised capacities for generators GN01 and GN03.

Facility Description [326 IAC 2-7-5(15)]:

(1) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as LES #1 and LES#2, located in Building A.
(2) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as HSS-01BR and HSS-02BR, located in Building A.
(3) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as Bryan #1 and Bryan #2, located in Building C.
(4) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as HSS-03BR, located in Building C.
(5) One (1) 0.88 MMBtu/hr natural gas tangential fired boiler, identified as BLDG E Boiler, located in Building E.
(6) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BLDG F Boiler, located in Building F.
(7) Two (2) 3.81 MMBtu/hr natural gas fired boilers, identified as D-1 and D-2, located in Building D.
(~~7~~**8**) One (1) ~~74.32~~ **5.59** MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN03, providing service to Buildings A and C.
(~~8~~**9**) One (1) ~~6.93~~ **0.56** MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN01, providing service to Building B.
(10) One (1) 5.97 MMBtu/hr natural gas emergency generator, identified as GN02, providing service to Building D.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

(3) Condition D.2.1 shall be changed as follows to reflect the revised PM limit of 0.40 lb/MMBtu.

D.2.1 Particulate Matter Emissions [326 IAC 6-2-4]

The owner or operator shall, for boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, and BLDGF, limit the PM emissions from each unit to 0.4~~2~~**0** lb/MMBtu or less.

Comment 2:

Condition A.2(a)(5) lists the capping operations in Building B when they actually occur in buildings A and C. This should be corrected.

Response 2:

The capping operation descriptions shall be changed as requested. To incorporate the proposed change into the permit the following changes shall be made.

(1) Condition A.2 shall be changed as follows to reflect the revised building reference for the capping process.

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

(a) One (1) pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A and C, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;

.....

(5) One (1) ancillary capping process, located in Building**s** ~~B~~**A and C**, applying a cap in each vial or syringe in preparation for final packaging; and

(2) The unit description of D.1 shall be changed as follows to reflect the revised building reference for the capping process.

Facility Description [326 IAC 2-7-5(15)]:

The pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A and C, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;

.....

(5) One (1) ancillary capping process, located in Building**s** ~~B~~**A and C**, applying a cap in each vial or syringe in preparation for final packaging; and

.....

Comment 3:

Baxter Pharmaceutical assumes from the discussion on Page 12 of the draft permit TSD under the title "326 IAC 6-2-4 (Particulate Matter Emissions from Source of Indirect Heating)" that Section D.2.1 Particulate Matter Emissions requires no ongoing demonstration of compliance by the facility. Baxter pharmaceutical requests confirmation of this assumption.

Response 3:

326 IAC 6-2-4 requires only that the PM emissions of each affected boiler be limited to 0.40 lb/MMBtu. Since compliance with the limit has been demonstrated via emissions calculations, no further demonstration of compliance is necessary at this time. The Office of Air Quality does, however, have the authority to require stack testing if deemed necessary.

Comment 4:

Condition D.1.1 requires the facility to prepare a Preventive Maintenance Plan in accordance with Section B - Preventive Maintenance Plan. Section B.9(a)(1) requires identification of individuals responsible for inspecting, maintaining, and repairing emission control devices. At present, the facility does not have any emission control devices, so Baxter Pharmaceuticals is requesting clarification as to which units this condition applies.

Response 4:

The source is required to have a preventive maintenance plan pursuant to 326 IAC 1-6-3. Pursuant to 326 IAC 1-6-3, any person responsible for operating any facility specified in 326 IAC 1-6-1 shall prepare and maintain a preventive maintenance plan.

Pursuant to 326 IAC 1-6-1, this rule applies to the owner or operator of any facility required to obtain a construction permit under 326 IAC 2-5.1 or a minor source operating permit under 326 IAC 2-6.1.

Since the source is required to obtain a minor source operating permit under 326 IAC 2-6.1-2, the source is required to have a preventive maintenance plan for all of the source emission units and control devices.

The preventive maintenance plan requirements specified in Condition D.1.1 apply to the emission units and control devices listed in the unit description of Section D.1. The preventive maintenance plan requirements specified in Condition D.2.2 apply to the emission units and control devices listed in the unit description of Section D.2.

Comment 5:

Regarding Condition C.3, since the facility's boilers all burn natural gas and only infrequently used emergency generators burn diesel, we assume that no formal measurement of opacity is required.

Response 5:

Condition C.3 establishes the opacity limits associated with 326 IAC 5-1. No stack testing or monitoring is required at this time. The Office of Air Quality does, however, have the authority to require demonstration of compliance if deemed necessary.

On January15, 2004, Baxter submitted the following supplemental comments. The following lists the comments, the responses to the comments, and all changes that have been made as a result of the comments. All added information is indicated in bold type. All deleted information is struck-out.

Comment 1:

Upon review of the comments and responses of the Addendum to the Technical Support Document and the proposed permit, it was discovered that the information submitted for the generators was incorrect and thus the following changes are requested.

(a) Please change the fuel combusted in generator GN01 from No. 2 fuel to natural gas.
(b) Please identify GN03 as GN02.
(c) Please identify GN02 as GN05 and change the fuel combusted from natural gas to No. 2 fuel oil.

Response 1:

The unit identifications and fuel changes shall be made as proposed. No other changes are necessary as a result of the proposed changes. Therefore the changes shall be made as proposed.

Changing the fuel of GN01 requires re-determining the emissions from these units and changing the unit descriptions.

The emissions from GN01 based on No. 2 fuel oil combustion was determined to be the following.

	PM	PM10	SO2	NOx	VOC	CO
Tons/yr	**-**	**0.04**	**0.04**	**0.62**	**0.05**	**0.13**

The emissions from GN01 based on natural gas combustion is determined to be the following. The emissions are determined based on a maximum capacity of 0.56 MMBtu/hr, dual fuel emissions factors for large stationary duel fuel internal combustion engines because the emission factors are the best emission factors available and the duel fuel engine emission factors are determined based on 95% natural gas combustion, a sulfur content of 0.5% for natural gas, emissions before controls, and 500 hours of operation.

0.56 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons pollutant per year

	PM	PM10	SO2	NOx	VOC	CO
Ef lb/MMBtu	ND	ND	0.44	2.70	0.80	1.16
Tons/yr	**-**	**-**	**0.06**	**0.38**	**0.11**	**0.16**

The emissions are uncontrolled and there are no limits or standards associated with the generator.

The adjusted emissions for generator GN01 are as follows:

	PM	PM10	SO2	NOx	VOC	CO
Old Emissions (tons/yr)	-	0.04	0.04	0.62	0.05	0.13
New Emissions (tons/yr)	-	-	0.06	0.38	0.11	0.16
Adjusted Emissions for GN01	**-**	**-0.04**	**+0.02**	**-0.24**	**+0.06**	**+0.03**

No emission calculations are necessary to change the unit description of GN02 (now GN05) from natural gas to No. 2 fuel oil because the emissions were determined based on No. 2 fuel oil combustion but the unit descriptions incorrectly identified the fuel combusted as natural gas.

The adjusted source emissions are as follows:

Pollutant	Potential To Emit (tons/year)
PM	0.89

PM10	1.87
SO2	3.10
VOC	24.35
CO	22.31
NO_x	39.91

Pollutant	Potential To Emit (tons/year)
Worst Case Single HAP*	0.37
Combined HAPs*	0.38

* The changes requested under this comment will not affect the source HAP emissions because the individual and combined HAP emissions from generator GN01 using natural gas and No. 2 fuel oil are determined to be negligible.

To incorporate the proposed changes, the following changes shall be made.

(1) Condition A.2 shall be changed as follows to change GN03 to GN02, change GN02 to GN05, change the fuel combusted in GN01 from No. to fuel oil to natural gas and change the fuel combusted in GN02 (now GN05) from natural gas to No. 2 fuel oil.

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

(a) One (1) pharmaceutical manufacturing operation consisting of:

.....

(i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN0~~3~~**2**, providing service to Buildings A and C.

(j) One (1) 0.56 MMBtu/hr ~~No. 2 fuel oil~~ **natural gas** fired emergency generator, identified as GN01, providing service to Building B.

(k) One (1) 5.97 MMBtu/hr ~~natural gas~~ **No. 2 fuel oil fired** emergency generator, identified as GN0~~2~~**5**, providing service to Building D.

(2) The unit description of Section D.2 shall be changed as follows to change GN03 to GN02, change GN02 to GN05, change the fuel combusted in GN01 from No. 2 fuel oil to natural gas and change the fuel combusted in GN02 (now GN05) from natural gas to No. 2 fuel oil.

Facility Description [326 IAC 2-7-5(15)]:

(1) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as LES #1 and LES#2, located in Building A.

…….

(8) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN03**2**, providing service to Buildings A and C.
(9) One (1) 0.56 MMBtu/hr ~~No. 2 fuel oil~~ **natural gas** fired emergency generator, identified as GN01, providing service to Building B.
(10) One (1) 5.97 MMBtu/hr ~~natural gas~~ **No. 2 fuel oil fired** emergency generator, identified as GN02~~2~~**5**, providing service to Building D.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Comment 2:

Please identify the mixing and formula, ancillary product filtration, vial or syringe preparation, product filling, and capping processes as being located in buildings A and D.

Response 2:

The changes shall be made as requested to Condition A.2 and the unit description of Section D.1.

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

(a) One (1) pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A and ~~C~~**D**, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;

(2) One (1) ancillary product filtration process, located in Buildings A and ~~C~~**D**, removing suspended solids from the pharmaceuticals in preparation for packaging;

(3) One (1) vial or syringe preparation process, located in Buildings A and ~~C~~**D**, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;

(4) One (1) ancillary product filling process, located in Buildings A and ~~C~~**D**, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;

(5) One (1) ancillary capping process, located in Buildings A and ~~C~~**D**, applying a cap in each vial or syringe in preparation for final packaging; and

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

The pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A and ~~C~~**D**, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
(2) One (1) ancillary product filtration process, located in Buildings A and ~~C~~**D**, removing suspended solids from the pharmaceuticals in preparation for packaging;
(3) One (1) vial or syringe preparation process, located in Buildings A and ~~C~~**D**, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
(4) One (1) ancillary product filling process, located in Buildings A and ~~C~~**D**, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
(5) One (1) ancillary capping process, located in Buildings A and ~~C~~**D**, applying a cap in each vial or syringe in preparation for final packaging; and
(6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

On February 16, 2004, Baxter submitted the following final supplemental comment. The following lists the comment, the response to the comment, and all changes that have been made as a result of the comment. All added information is indicated in bold type. All deleted information is struck-out.

Comment 1:

Please identify the mixing and formula, ancillary product filtration, vial or syringe preparation, product filling, and capping processes as being located in buildings A, “C”, and D.

Response 1:

The changes shall be made as requested to Condition A.2 and the unit description of Section D.1.

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

(a) One (1) pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A**, C,** and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
(2) One (1) ancillary product filtration process, located in Buildings A**, C,** and D, removing suspended solids from the pharmaceuticals in preparation for packaging;
(3) One (1) vial or syringe preparation process, located in Buildings A**, C,** and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
(4) One (1) ancillary product filling process, located in Buildings A**, C,** and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
(5) One (1) ancillary capping process, located in Buildings A**, C,** and D, applying a cap in each

vial or syringe in preparation for final packaging; and

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

The pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A**, C,** and **D**, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
(2) One (1) ancillary product filtration process, located in Buildings A**, C,** and **D**, removing suspended solids from the pharmaceuticals in preparation for packaging;
(3) One (1) vial or syringe preparation process, located in Buildings A**, C,** and **D**, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
(4) One (1) ancillary product filling process, located in Buildings A**, C,** and **D**, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
(5) One (1) ancillary capping process, located in Buildings A**, C,** and **D**, applying a cap in each vial or syringe in preparation for final packaging; and
(6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a Minor Source Operating Permit

Source Background and Description

Source Name:	Baxter Pharmaceutical Solutions LLC
Source Location:	927 South Curry Pike, Bloomington, Indiana 47403
County:	Monroe
SIC Code:	2834
Operation Permit No.:	105-16441-00040
Permit Reviewer:	SDF

The Office of Air Quality (OAQ) has reviewed an application from Baxter Pharmaceutical Solutions LLC relating to the construction and operation of a third party pharmaceutical manufacturing operation.

Request

On August 9, 2002, Baxter Pharmaceutical Solutions LLC submitted an application to construct and operate:

(a) One (1) pharmaceutical manufacturing operation consisting of:

(1) One (1) mixing and formulation process, located in Buildings A and C, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;

(2) One (1) ancillary product filtration process, located in Buildings A and C, removing suspended solids from the pharmaceuticals in preparation for packaging;

(3) One (1) vial or syringe preparation process, located in Buildings A and C, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;

(4) One (1) ancillary product filling process, located in Buildings A and C, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;

(5) One (1) ancillary capping process, located in Buildings A and C, applying a cap in each vial or syringe in preparation for final packaging; and

(6) One (1) ancillary final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

(b) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as LES #1 and LES#2, located in Building A.

(c) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as HSS-01BR and HSS-02BR, located in Building A.

(d) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as Bryan #1 and Bryan #2, located in Building C.

(e) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as HSS-03BR, located in Building C.

(f) One (1) 0.88 MMBtu/hr natural gas tangential fired boiler, identified as BLDG E Boiler, located in Building E.

(g) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BLDG F Boiler, located in Building F.

(h) Two (2) 3.81 MMBtu/hr natural gas fired boilers, identified as D-1 and D-2, located in Building D.

(i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN03, providing service to Buildings A and C.

(j) One (1) 0.56 MMBtu/hr natural gas normal fired emergency generator, identified as GN01, providing service to Building B.

(k) One (1) 5.97 MMBtu/hr natural gas emergency generator, identified as GN02, providing service to Building D.

Existing Approvals

This is the first approval for the source.

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the Minor Source Operating Permit be approved. This recommendation is based on the following facts and conditions. Unless otherwise stated, information used in this review was derived from the application.

Emission Calculations

(a) Unrestricted Potential to Emit (UPTE):

The emissions generated by the proposed source are the VOC emissions from the equipment of the pharmaceutical manufacturing operation and the source combustion unit criteria and hazardous air pollutant emissions. The following calculations determine the emissions from these units.

(1) Pharmaceutical Manufacturing Operation:

(A) Mixing and Formulation Process:

The mixing and formulation process generates VOC emissions.

The following calculations determine the VOC unrestricted potential to emit based on the estimated maximum hourly rates, emissions before controls, and a maximum batch operation time of 6240 hours of operation.

X lb/hr * 6240 hr/yr * 1/2000 ton/lb = tons/yr

VOC	Max. Rate (lb/hr)	Emissions (tons/yr)
Phenol	0.002	0.01
Benzyl Alcohol	0.273	0.85
Ethanol	0.106	0.33
Acetone	0.104	0.32
Metacresol	0.007	0.02
	Total	**1.53**

There are no materials used that contain any regulated hazardous air pollutants other than phenol.

(B) Product Filtration Process:

The product filtration process is determined to be an ancillary process with no emissions associated with the affected equipment.

(C) Vial/Syringe Preparation Process:

Isopropyl alcohol is used to decontaminate the vials and syringes that are used as containers for the pharmaceuticals produced. Isopropyl alcohol is a volatile organic compound.

The following calculations determine the isopropyl alcohol unrestricted potential to emit based on the estimated maximum hourly rate, emissions before controls, and a maximum batch operation time of 6240 hours of operation.

X lb/hr * 6240 hr/yr * 1/2000 ton/lb = tons/yr

VOC	Max. Rate (lb/hr)	Emissions (tons/yr)
Isopropyl Alcohol	6.71	**20.94**

(D) Filling Process:

The filling process is determined to be an ancillary process with no emissions associated with the affected equipment.

(E) Capping Process:

The capping process is determined to be an ancillary process with no emissions associated with the affected equipment.

(F) Final Packing Process:

The packing process is determined to be an ancillary process with no emissions associated with the affected equipment.

(2) Combustion Emissions:

The following table lists the combustion unit criteria pollutant unrestricted potential to emit (UPTE) determined using the IDEM combustion spreadsheets (AP-42 emission factors) or as specifically identified.

Criteria Pollutants:

Unit	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	VOC (tons/yr)	NOx (tons/yr)	CO (tons/yr)
LES#1	0.01	0.04	neg.	0.03	0.47	0.40
LES#2	0.01	0.04	neg.	0.03	0.47	0.40
HSS-02BR	0.06	0.24	0.02	0.18	3.21	2.70
HSS-01BR	0.06	0.24	0.02	0.18	3.21	2.70
Bryan#1	0.02	0.10	0.01	0.07	1.31	1.10
Bryan#2	0.02	0.10	0.01	0.07	1.31	1.10
HSS-03BR	0.12	0.49	0.04	0.35	6.44	5.41
BLDGE	0.01	0.03	neg.	0.02	0.39	0.32
BLDGF	neg.	0.01	neg.	0.01	0.20	0.17
D-1	neg.	0.10	neg.	0.10	1.70	1.40
D-2	neg.	0.10	neg.	0.10	1.70	1.40
GN01*	-	0.04	0.04	0.05	0.62	0.13
GN02**	0.15	0.09	0.75	0.15	4.78	1.27
GN03***	0.14	0.08	0.70	0.14	4.47	1.19
Total	**0.60**	**1.70**	**1.59**	**1.48**	**30.28**	**19.69**

*** GN01 Emergency Generator Emissions:**

The GN01 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 0.56 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

0.56 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons pollutant per year

	PM	PM10	SO2	NOx	VOC	CO
Ef lb/MMBtu	ND	0.31	0.29	4.41	0.36	0.95

Tons/yr	-	**0.04**	**0.04**	**0.62**	**0.05**	**0.13**

ND = not determined

**** GN02 Emergency Generator Emissions:**

The GN02 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 5.97 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

5.97 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons pollutant per year

	PM	PM10	SO2	NOx	VOC	CO
UPTE (tons/yr)	0.1	0.06	0.5	3.2	0.1	0.85
Tons/yr	**0.15**	**0.09**	**0.75**	**4.78**	**0.15**	**1.27**

***** GN03 Emergency Generator Emissions:**

The GN03 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 5.59 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

5.59 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons/yr

	PM	PM10	SO2	NOx	VOC	CO
UPTE (tons/yr)	0.1	0.06	0.5	3.2	0.1	0.85
Tons/yr	**.14**	**.08**	**.70**	**4.47**	**.14**	**1.19**

Hazardous Air Pollutants (HAP):

Boilers:

The following table lists the boiler hazardous air pollutant unrestricted potential to emit (UPTE) determined using the IDEM combustion spreadsheets (AP-42 emission factors) or as specifically identified.

Pollutant	D1	D2	02BR	01BR	Bryan1	Bryan2	03BR	BLDGF	LES1	BLDGE	LES2	Total
Acetylaldehyde	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	neg.
Acrolein	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	neg.
Benzene	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Dichlorobenz	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Formaldehyde	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Hexane	0.03	0.03	0.06	0.06	0.02	0.02	0.12	neg.	0.01	0.01	0.01	**0.37**
Napthalene	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	neg.

Propylene	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	neg.
Toluene	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Lead	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Cadmium	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Chromium	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Manganese	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Nickel	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
Xylene	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	neg.
											Total	0.37

GN01 Emergency Generator Emissions:

The GN01 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 0.56 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

0.56 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons/yr

	Ef lb/MMBtu	tons/yr
Acetylaldehyde	7.67E-4	neg.
Acrolein	9.25E-5	neg.
Benzene	9.33E-4	neg.
Formaldehyde	1.18E-3	neg.
Propylene	2.58E-3	neg.
Toluene	4.09E-4	neg.
Xylene	2.85E-4	neg.
1, 3 Butadiene	3.91 E-5	neg.
Naphthalene	8.48E-5	neg.
	Total	**neg.**

GN02 Emergency Generator Emissions:

The GN02 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 5.97 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

5.97 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons/yr

	Ef lb/MMBtu	tons/yr

Acetylaldehyde	2.52E-5	neg.
Acrolein	7.88E-6	neg.
Benzene	7.76E-4	neg.
Formaldehyde	7.89E-5	neg.
Propylene	2.79E-3	neg.
Toluene	2.81E-4	neg.
Xylene	1.93E-4	neg.
Naphthalene	1.30E-4	neg.
	Total	**neg.**

GN03 Emergency Generator Emissions:

The GN03 emergency generator emissions are determined as follows based on No. 2 fuel oil combustion, a maximum capacity of 5.59 MMBtu/hr, AP-42 emission factors, emissions before controls, and 500 hours of operation.

5.59 MMBtu/hr * Ef lb/MMBtu * 500 hr/yr * 1/2000 ton/lb = tons/yr

	Ef lb/MMBtu	tons/yr
Acetylaldehyde	2.52E-5	neg.
Acrolein	7.88E-6	neg.
Benzene	7.76E-4	neg.
Formaldehyde	7.89E-5	neg.
Propylene	2.79E-3	neg.
Toluene	2.81E-4	neg.
Xylene	1.93E-4	neg.
Naphthalene	1.30E-4	neg.
	Total	**neg.**

(b) Emissions After Controls:

None of the emissions are controlled. Thus, the emissions after controls equal the estimated emissions before controls.

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U.S. EPA."

This table reflects the PTE before controls from the source based on the above estimated emissions calculations. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	0.60
PM10	1.70
SO2	1.59
VOC	23.95
CO	19.69
NO_x	30.28

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

Pollutant	Potential To Emit (tons/year)
Worst Case Single HAP	0.37
Combined HAPs	0.38

All criteria pollutant UPTE are less than 100 tons/yr, no single HAP emissions exceed 10 tons/yr, and the combined HAP emissions do not exceed 25 tons/yr. However, the NOx and VOC unrestricted potential to emit (UPTE) exceed the Minor Source Operating Permit (MSOP) applicable level of 25 tons per year and less than the Part 70 applicable level of 100 tons per year. Therefore, the proposed source shall be permitted under a Minor Source Operating Permit (MSOP) pursuant to 2-6.1-2.

County Attainment Status

The source is located in Monroe County.

Pollutant	Status
PM_{10}	attainment or unclassifiable
SO_2	attainment or unclassifiable
NO_2	attainment or unclassifiable
Ozone	attainment or unclassifiable
CO	attainment or unclassifiable
Lead	attainment or unclassifiable

(a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards.

Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, the VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration, 326 IAC 2-2.

(b) Monroe County has been classified as attainment or unclassifiable for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(c) Fugitive Emissions

Since this type of operation is one of the 28 listed source categories under 326 IAC 2-2, fugitive PM emissions are counted toward determination of PSD applicability and the major source PSD levels for all applicable pollutants is reduced from 250 to 100 tons per year.

Source Status

New Source PSD Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	NOx (tons/yr)	VOC (tons/yr)	CO (tons/yr)	Single HAP (tons/yr)	Comb. HAPs (tons/yr)
Source	0.60	1.70	1.59	30.28	23.95	19.69	0.37	0.38

PSD Major Levels	100	100	100	100	100	100	-	-
Part 70 Major Levels	-	100	100	100	100	100	10	25

(a) This new source is not a major PSD stationary source because no attainment regulated pollutant is emitted at a rate of 100 tons per year or more.

(b) This new source is not a Title V major stationary source because no criteria pollutant UPTE exceeds the applicable level of 100 tons/yr, the single HAP UPTE is less than the applicable level of 10 tons/yr, and the combined HAP UPTE is less than the applicable level of 25 tons/yr.

Federal Rule Applicability

(a) New Source Performance Standards (NSPS):

(1) 40 CFR 60, Subpart III, Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes:

Pursuant to 60.110(a) of Subpart III, the provisions of this Subpart apply to each affected facility designated in paragraph (b) of this Section that produces any of the chemicals listed in 60.617 as a

product, co-product, by-product, or intermediate.

The requirements of 40 CFR 60, Subpart III do not apply to the equipment of the proposed source because the source will not produce any of the chemicals listed in 60.117 as a product, co-product, by-product, or intermediate.

(2) 40 CFR 60, Subpart NNN, Standards of Performance for Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry Distillation Operations:

Pursuant to 60.660(a) of Subpart NNN, the provisions of this Subpart apply to each affected facility described in paragraph (b) of this Section that is a part of a process unit that produces any of the chemicals listed in 60.667 as a product, co-product, by-product, or intermediate.

The requirements of 40 CFR 60, Subpart NNN do not apply to the equipment of the proposed source because the source will not produce any of the chemicals listed in 60.667 as a product, co-product, by-product, or intermediate.

(3) 40 CFR60, Subpart RRR, Standards of Performance for Volatile Organic Compound Emissions From Synthetic Organic Chemical Manufacturing Industry Reactor Processes:

Pursuant to 60.700 of Subpart RRR, the provisions of this Subpart apply to each affect facility designated in paragraph (b) of this Section that is a part of a process unit that produces any of the chemicals listed in 60.707 as a product, co-product, by-product, or intermediate.

The requirements of 40 CFR, Subpart RRR do not apply to the equipment of the proposed source because the source will not produce any of the chemicals listed in 60.707 as a product, co-product, by-product, or intermediate.

(4) 40 CFR 60, Subpart VV, Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry:

Pursuant to 60.480 of Subpart VV, the provisions of this Subpart apply to affected facilities in the synthetic organic chemicals manufacturing industry.

The requirements of 40 CFR 60, Subpart VV do not apply to the equipment of the proposed source because the source is not part of the synthetic organic chemicals manufacturing industry.

(5) 40 CFR 60, Subpart D, Standards of Performance for Fossil-Fuel-Fired Steam Generators for Which Construction is Commenced After August 17, 1971:

Pursuant to 60.40(a) of Subpart D, the affected facilities to which the provisions of this Subpart apply are each fossil-fuel-fired steam generating unit of more than 250 MMBtu/hr and each fossil fuel and wood residue fired steam generating unit capable of firing fossil fuel at a heat input rate of more than 250 MMBtu/hr.

The requirements of Subpart D do not apply to any of the boilers of the source because none of the proposed boilers have a capacity greater than 250 MMBtu/hr.

(6) 40 CFR 60, Subpart Da, Standards of Performance for Electric Utility Steam Generating Units for Which Construction is Commenced After September 18, 1978:

Pursuant to 60.40a(a) of Subpart Da, the affected facility to which this Subpart applies is each electric utility steam generating unit that is capable of combusting more than 250 MMBtu/hr heat input of fossil fuel and for which construction or modification is commenced after September 18, 1978.

The requirements of Subpart Da do not apply to any of the boilers of the source because none of the proposed boilers have a capacity greater than 250 MMBtu/hr.

(7) 40 CFR 60, Subpart Db, Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units:

Pursuant to 60.40b(a) of Subpart Db, the affected facility to which this Subpart applies is each steam generating unit that commences construction, modification, or reconstruction after June 19, 1984, and that has a heat input capacity from fuels combusted in the steam generating unit of greater than 100 MMBtu/hr.

The requirements of Subpart Db do not apply to any of the boilers of the source because none of the proposed source boilers have a capacity greater than 100 MMBtu/hr.

(8) 40 CFR 60, Subpart Dc, Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units:

Pursuant to 60.40c(a) of Subpart Dc, the affected facility to which this Subpart applies is each steam generating unit for which construction, modification, or reconstruction is commenced after June 9, 1989 and that has a maximum design heat input capacity of 100 MMBtu/hr or less but greater than or equal to 10 MMBtu/hr.

Boiler HSS-03BR has a capacity greater than the low end applicable capacity of 10 MMBtu/hr. However, since the boiler will combust natural gas, there are no applicable Subpart Dc standards, performance testing, or monitoring requirements that apply.

However, upon review of the remaining requirements, it is determined that the notification and record keeping requirements of 60.48c(a), (g), and (i), apply because these requirements apply to any affected facility specified in 60.40c. Boiler HSS-03BR is an affected facility under 40 CFR 60.40c.

Pursuant to 60.48c(a), the owner or operator shall submit to the Office of Air Quality, a notification regarding Boiler HSS-03BR. Said notification shall include:

(a) the date of construction or reconstruction, the date of anticipated startup, and the date of actual startup, as provided in 40 CFR 60.7; and

(b) the design heat input capacity of the boiler and identification of the fuels combusted in the boiler.

Pursuant to 60.49c(g) and (i), the owner or operator shall, for Boiler HSS-03BR, record and maintain records of the amount of each fuel combusted during each day.

Said records shall be maintained for a minimum period of two years following the date the information is recorded.

The requirements of Subpart Dc do not apply to any of the other boilers of the source because each of the remaining proposed boilers have a capacity less than the low end applicable level of 10 MMBtu/hr.

(b) National Emission Standards for Hazardous Air Pollutants (NESHAPs):

(1) 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceuticals Production:

Pursuant to 63.1250 of Subpart GGG, the affected source subject to this part pharmaceutical manufacturing operations which:

(a) manufactures a pharmaceutical product as defined in 63.1251,
(b) is a major source as defined in Section 112(a) of the ACT, and
(c) processes, uses, or produces hazardous air pollutant.

The requirements of 40 CFR 63, Subpart GGG do not apply to the equipment of the proposed source because the source does not process, use, or produce hazardous air pollutants and is not a major source as defined in Section 112(a) of the Act.

(2) 40 CFR 63, Subparts F, G, and H, National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry:

Pursuant to 63.100(a) of Subpart F, this Subpart provides the applicability provisions, definitions, and other general provisions that are applicable to Subparts F, G, and H of Part 63.

Pursuant to 63.100(b) of Subpart F, the provisions of Subparts F, G, and H of Part 63 apply to chemical manufacturing process units that meet all of the following criteria:

(a) manufacture as a primary product one or more of the chemicals listed in paragraphs (b)(1)(i) or (b)(1)(ii),

(b) use as a reactant or manufacture as a product or co-product, one or more of the organic hazardous air pollutants listed in Table 2 of Subpart F, and

(c) are located at a plant site that is a major source as defined in Section 112(a) of the Act.

The requirements of 40 CFR 63, Subparts F, G, and H do not apply to the equipment of the

proposed source because the source is not a major source as defined in Section 112(a) of the Act.

(3) 40 CFR 63, Subpart I, National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks:

Pursuant to 63.190(b) of Subpart I, the provisions of Subparts I and H of Part 63 apply to emissions of the designated organic HAP from the processes specified in paragraphs (b)(1) through (b)(6) of this section that are located at a plant site that is a major source as defined in Section 112(a) of the Act.

The requirements of 40 CFR 63, Subparts I and H do not apply to the units of the source because the source is not a major source as defined in Section 112(a) of the Act.

State Rule Applicability

(a) Entire Source Rules:

(1) 326 IAC 1-6-3 (Preventive Maintenance Plan):

The proposed source is required to have a preventive maintenance plan for the emission units and control devices of the source.

(2) 326 IAC 2-2 (Prevention of Significant Deterioration):

The requirements of 326 IAC 2-2 do not apply because no attainment regulated pollutant is emitted at a rate of 100 tons per year or more.

(3) 326 IAC 2-4.1 (HAP Major Sources):

This source is not subject to the requirements of 326 IAC 2-4.1 because no single hazardous air pollutant (HAP) emissions exceed 10 tons per year, and the combined HAP emissions are less than 25 tons per year.

(4) 326 IAC 2-6 (Emission Reporting):

This source is not subject to the requirements of 326 IAC 2-6 (Emission Reporting), because none of the affected pollutant emissions exceed the Monroe County applicable level of 100 tons per year.

(5) 326 IAC 5-1-2 (Opacity Limitations):

This source is subject to the requirements of 326 IAC 5.

Opacity shall not exceed an average of 40% in any one 6 minute averaging period. Opacity shall not exceed 60% for more than a cumulative total of fifteen minutes.

(b) Individual Unit Rules:

(1) 326 IAC 6-2-4 (Particulate Matter Emissions from Sources of Indirect Heating):

Pursuant to 326 IAC 6-2-4(d), particulate emissions from the combustion of fuel for indirect heating

from all facilities receiving permits to construct on or after September 21, 1983 shall be limited by 326 IAC 6-2-4.

The requirements of 326 IAC 6-2-4 apply to Boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, D-1, and D-2 because the boilers are sources of indirect heating that will be constructed after the applicable date of September 21, 1983.

Pursuant to 326 IAC 6-2-4, particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

Pt = [1.09] / [Q]^0.26

where: Pt = limit, pounds of particulate matter emitted per million Btu (lb/MMBtu)
Q = total source maximum operating capacity rating in MMBtu/hr heat input (46.46)

The PM emissions from boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, D-1, and D-2, each, shall be limited to 0.40 lb/MMBtu.

The PM emissions from boilers LES #1, LES #2, HSS-01BR, HSS-02BR, Bryan #1, Bryan #2, HSS-03BR, BLDGE, BLDGF, D-1, and D-2, each, are determined to be 0.002 lb/MMBtu which is less than the limit of 0.40 lb/MMBtu.

1.9 lb PM/MMcf * 1 MMcf/1000 MMBtu = 0.002 lb PM/MMBtu

Therefore, compliance with the limit of 326 IAC 6-2-4 is still determined to be achieved.

(2) 326 IAC 7 (Sulfur Dioxide Emission Limitations):

Pursuant to 326 IAC 7-1.1-1, all facilities with a potential to emit twenty-five (25) tons per year or 10 (10) pounds per hour of sulfur dioxide shall comply with the limitations of Section 2 of this rule and the compliance test methods in 326 IAC 7-2 unless alternative limitations and requirements have been established in a Part 70 permit in accordance with 326 IAC 2-7-24. The above facilities shall also comply with the sulfur dioxide emission limitations and other requirements pursuant to 326 IAC 2, 326 IAC 7-4, and 326 IAC 12, unless alternative limitations and requirements have been established in a Part 70 permit in accordance with 326 IAC 2-7-24.
The requirements of 326 IAC 7 do not apply because there are no emission units with a SO2 potential to emit greater than 25 tons per year.

(3) 326 IAC 8-5-3 (Miscellaneous Operations, Synthesized Pharmaceutical Manufacturing Operations):

Pursuant to 326 IAC 8-5-3(a), this Section applies to the manufacture of pharmaceutical products by chemical synthesis. This Section applies to all facilities emitting volatile organic compounds including reactors, distillation units, dryers, storage of volatile organic compounds, transfer of volatile organic compounds, extraction equipment, filters, crystallizers, and centrifuges that have the potential to emit six and eight-tenths (6.8) kilograms per day (fifteen (15) pounds per day) or more.

The requirements of 326 IAC 8-5-3 do not apply to the equipment of the source because the source

does not have any reactors, distillation units, dryers, storage of volatile organic compounds, transfer of volatile organic compounds (VOC), extraction equipment, filters, crystallizers, and centrifuges that generate VOCs.

(4) 326 IAC 8-1-6 (State Best Available Control Technology Requirements):

Although there are no other Article 8 rule that apply, 326 IAC 8-1-6 does not apply to the mixing and formulation and vial or syringe preparation processes because the estimated VOC UPTE (1.53 and 20.94 tons/yr), each, are less than the applicable level of 25 tons per year.

Conclusion

The proposed source shall be constructed and operated according to the provisions of Minor Source Operating Permit (MSOP) 105-16441-00040.